IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Stamm et al**

Application No. **10/665,522** Group Art Unit: **1615**

Filed: **September 22, 2003** Examiner: **Sheikh**

For: **Fenofibrate Compositions Having Enhanced Bioavailability**

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Information Disclosure Statement

Pursuant to 37 CFR §§ 1.56, 1.97 and 1.98, Applicants bring to the attention of the Examiner the documents listed on the attached PTO-1449 Form. A copy of the Non Patent Literature Documents and the Foreign Patent Documents is attached hereto.

Applicants direct the Examiner's attention to:

(a) Cite No. 1 on PTO-1449 Form No. 1 of 9, the dissolution profile on page 12 at Table VII in Laboratoires Fournier's undated document entitled "Fenofibrate Tablets 54-160 MG Dissolution Test Conditions Development Studies, Dissolution Test Specification Recommendations."

(b) Cite No. 24 on PTO-1449 Form 3 of 9, the Declaration under 37 CFR § 1.132 by Phillippe Reginault filed in US Application No. 10/288,425 on March 7, 2005.

(c) *In re TriCor Indirect Purchaser Antitrust Litigation*, District of Delaware, Civil Action No. 05-360.

(d) *CVS Pharmacy, Inc. et al. v. Abbott Laboratories et al*, District of Delaware, 1:05-cv-00605-KAJ.

(e) *Walgreen Co. et al v. Abbott Laboratories et al*, District of Delaware, 1:05-cv-00404-KAJ.

(f) *Pacificare Health Systems, Inc. v. Abbott Laboratories et al*, District of Delaware, 1:05-cv-00591-KAJ.

(g) *Painters District Council No. 30 Health and Welfare Fund et al v. Abbott Laboratories et al*, District of Delaware, 1:05-cv-00360-KAJ.

(h) *Louisiana Wholesale Drug Company, Inc. v. Abbott Laboratories et al*, District of Delaware, 1:05-cv-00340-KAJ;

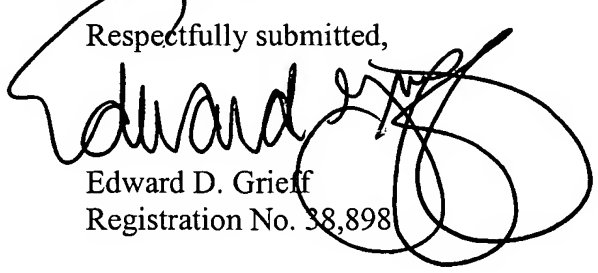
(i) *Paul T. Tegan v. Abbott Laboratories et al*, Central District of California, 2:05-cv-05410-GAF-AJW.

The submission of this Information Disclosure Statement does not represent that a search has been made and does not constitute an admission that the listed documents, oppositions and/or litigations are material to patentability or that the listed documents are prior art.

This Information Disclosure Statement is being filed after the mailing date of a first office action on the merits, but before a final office action or a notice of allowance. Accordingly, the Commissioner is authorized to charge the fee of **$180** to Deposit Account No. 22-0261. The Commissioner is authorized to charge any other necessary fees or credit any overpayments to Deposit Account No. 22-0261.

Applicants respectfully request that the PTO return an initialed copy of the PTO-1449 Form with the next communication from ~~the~~ Office.

Respectfully submitted,



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PTO/SB/08A (07-05)
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 4 of 4

Complete if Known	
Application Number	10/665,522
Filing Date	September 22, 2003
First Named Inventor	Stamm
Art Unit	1615
Examiner Name	Sheikh
Attorney Docket Number	224622

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 6,027,747	02-22-2000	Terracol et al	
		US- 5,633,015	05-27-1997	Gillis et al	
		US- 5,145,684	09-08-1992	Liversidge et al	
		US- 4,629,624	12-16-1986	Grouiller et al	
		US- 4,344,934	08-17-1982	Martin et al	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
		CA 2,142,848	03-17-1994	Janssen Pharmaceuticals		
		CA 960,670	01-07-1975	Orchimed SA		
		WO 98/31360	07-23-1998	Pharma Pass		
		WO 97/12581	04-10-1997	Pharma Pass		
		CA 2,219,475	07-09-2002	Laboratoires Fournier		
		CA 2,372,576	02-10-2004	Laboratoires Fournier		

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4

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Application Number	10/665,522
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First Named Inventor	Stamm
Art Unit	1615
Examiner Name	Sheikh
Attorney Docket Number	224622

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	1	Laboratoires Fournier undated document entitled "Fenofibrate Tablets 54-160 mg Dissolution Test Conditions Development Studies, Dissolution Test Specification Recommendations"	
	2	"Second Amended Answer, Affirmative Defenses, and Counterclaims" filed by Teva on 7-29-2005 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc. DE, CA No. 02-1512.	
	3	"First Amended Counterclaims" filed by Impax on 9-23-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	
	4	"Amended Complaint" filed by CVS Pharmacy et al on 9-23-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340.	
	5	"Amended Complaint" filed by Walgreen Co. et al on 9-23-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340.	
	6	"Amended Complaint" filed by Painters' District Council No. 30 et al on 9-23-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340.	
	7	"Amended Complaint" filed by Louisiana Wholesale Drug Co. et al on 10-3-2005 in In Re TriCor Direct Purchaser Antitrust Litigation, Delaware, CA No. 05-340.	
	8	"Defendant's Responses to Plaintiffs Interrogatories" filed by Impax on 8-6-2003 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	
	9	"Amended Answer" filed by Impax on 1-4-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	
	10	"Reply Memorandum" filed by Impax on 2-25-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	

Examiner Signature		Date Considered	

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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 4

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Application Number	10/665,522
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Art Unit	1615
Examiner Name	Sheikh
Attorney Docket Number	224622

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	11	"Memorandum Opinion" by District Judge Jordan dated 5-6-2005 in Abbott Laboratories et al v. Impax Laboratories, Inc., Delaware, CA No. 03-120-KAJ.	
	12	"Opening Brief in Support of Motion for Summary Judgment" by Teva filed on 12-23-2004 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., Delaware, CA No. 02-1512.	
	13	"Opening Brief in Support of Motion for Summary Judgment" by Teva filed on 12-10-2004 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., Delaware, CA No. 02-1512.	
	14	"Memorandum Opinion" by District Judge Jordan dated 5-6-2005 in Abbott Laboratories et al v. Teva Pharmaceuticals USA, Inc., Delaware, CA No. 02-1512.	
	15	Opposition to European Patent No. 1 273 293 filed 9-2-2005 by Ethypharm (French Language Docuement).	
	16	Opposition to Israel Patent No. 130790 filed 5-4-2005 by Teva; and Remarks in Response to Oppostion filed on 9-23-2005 (English language translations).	✓
	17	Munoz et al, Atherosclerosis, 110(Suppl.):S45-S48 (1994).	
	18	Pharmaceutical Pelletization Technology, Marcel Dekker, Inc., Volume 37, pages 1-13; 160-161; and 234-235 (1989).	
	19	Modern Pharmaceutics, Third Edition, Marcel Dekker, Inc., apges 131-133 and 335-356 (1996).	
	20	Pharmaceutical Dosage Forms, Tablets, Second Edition, Marcel Dekker, Inc., pages 5-28; 88-107; 133; 142; 160-165; and 260-267 (1989).	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 4

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Application Number	10/665,522
Filing Date	September 22, 2003
First Named Inventor	Stamm
Art Unit	1615
Examiner Name	Sheikh
Attorney Docket Number	224622

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	21	Shepherd Atherosclerosis, 110(Suppl.)S55-S63 (1994).	
	22	Adkins et al, Drugs, 54(4):615-633 (October 1997).	
	23	Letter from Teva/Novopharm to Fournier Pharma Inc. regarding Invalidity and Ambiguity of Canadian Patent Nos. 2,219,475 and 2,372,576 (pages 1-15)(September 19, 2005).	
	24	Declaration under 37 CFR 1.132 by Phillippe Reginault filed in US Application No. 10/288,425 on March 7, 2005.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2006

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) **180.00**

Complete if Known	
Application Number	10/665,522
Filing Date	September 22, 2003
First Named Inventor	Stamm
Examiner Name	Sheikh
Art Unit	1615
Attorney Docket No.	31672-224622

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 22-0261 Deposit Account Name: Venable LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

FEE CALCULATION (All the fees below are due upon filing or may be subject to a surcharge.)

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
Application Type	**Fee ($)**	**Small Entity Fee ($)**	**Fee ($)**	**Small Entity Fee ($)**	**Fee ($)**	**Small Entity Fee ($)**	**Fees Paid ($)**
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	**Fee ($)**	**Small Entity Fee ($)**
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims	- 20 or HP =	**Extra Claims**	x **Fee ($)**	= **Fee Paid ($)**

HP = highest number of total claims paid for, if greater than 20.

Multiple Dependent Claims

Fee ($)	**Fee Paid ($)**

Indep. Claims	- 3 or HP =	**Extra Claims**	x **Fee ($)**	= **Fee Paid ($)**

HP = highest number of total claims paid for, if greater than 3.

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	- 100 =	**Extra Sheets**	/50	**Number of each additional 50 or fraction thereof** (round up to a whole number)	x **Fee ($)**	= **Fee Paid ($)**

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g. late filing surcharge): X **Information Disclosure statement fee**	**$180.00**

SUBMITTED BY

Signature		Registration No. (Attorney/Agent) 38,898	Telephone
Name (Print/Type)	Edward D. Grieff		Date May 8, 2006

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete the form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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